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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,058	01/23/2006	Tushar A. Kshirsagar	C1271.70019US01	1950
23628	7590	11/07/2008		EXAMINER
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			RODRIGUEZ-GARCIA, VALERIE	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,058	<b>Applicant(s)</b> KSHIRSAGAR ET AL.
	<b>Examiner</b> VALERIE RODRIGUEZ-GARCIA	<b>Art Unit</b> 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 08/22/08.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 95, 97-98, 101, 103-104, 107-109, 111, 135-137 and 139-145 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18, 20, 21, 23, 25, 26, 29-32, 34, 36, 37, 40, 42, 43, 46-49, 63, 134 and 138 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 04/18/08.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

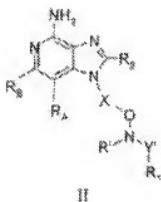
Continuation of Disposition of Claims: Claims pending in the application are 18,20,21,23,25,26,29-32,34,36,37,40,42,43,46-49,63,95,97,98,101,103,104,107-109,111 and 134-145.

**DETAILED ACTION**

***Status of the Claims***

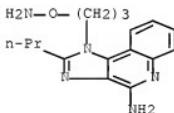
Claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 95, 97-98, 101, 103-104, 107-109, 111, 134-145 are currently pending. Claims 1-17, 19, 22, 24, 27, 28, 33, 35, 38, 39, 41, 44, 45, 50-62, 64-94, 96, 99-100, 102, 105-106, 110, 112-133 have been canceled by the Applicant. Claims 138-145 have been added.

1. Applicant's election without traverse of Group I, claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 134, 138 drawn to compounds of formula (II)



II

where R<sub>A</sub> and R<sub>B</sub> form a phenyl ring, in the reply filed on 08/22/08 is acknowledged. The following elected species is also acknowledged:



Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions

there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 08/22/08.

***Priority***

2. The current application is a 371 of PCT/US04/26158 filed on 08/12/2004, which claims benefit of provisional application 60/494608 filed on 08/12/2003 and provisional application 60/494605 filed on 08/12/2003.

***Note***

The species elected by the Applicant is free of the art. The search was extended to the entirety of the elected group.

Pursuant to Applicant's response, claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 134, 138 are treated on the merits in this action. This is the first Office Action on the merits of the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18, 20-21, 23, 25-26, 29-32, 34, 36-37, 40, 42-43, 46-49, 63, 134, 138 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Y'= a bond, -C(O)-, -C(S)-, -S(O)<sub>2</sub>-, -C(O)-O-, -C(O)-N(R<sub>8</sub>)-, -C(S)-N(R<sub>8</sub>)-, -C(O)-C(O)-, -C(O)-C(O)-O-; R<sub>2</sub>= H, alkyl or alkylethers; R<sub>1</sub>= H, alkyl, alkenyl, aryl, arylalkenyl, heteroaryl or heteroaryalkenyl; R'= H or alkyl does not reasonably provide enablement for the remaining scope of variable groups where for example R<sub>2</sub>

and R' are cycloalkyl or heteroaryl, or R<sub>1</sub> and R' together with the nitrogen form a ring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no reasonable basis for assuming that the myriad of compounds embraced by the all generic claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims recite a compound of formula (II) where R<sub>a</sub> and R<sub>b</sub> form a phenyl ring which compound contains many different variables. These are hydroxylamine substituted imidazoquinolines.

Breadth of the Claims: The claims cover millions of compounds given the number of possible chains, rings, ring systems covered by the claims scope along with varying choices for remaining variables.

State of the prior art: Prior art teaches imidazoquinolines substituted with alkylethers and alkylether alkylamide (US 7,427,629 B2). The claimed hydroxylamine substituted imidazoquinolines are not known in the prior art, neither their use nor activity. Nothing in

the prior art or current specification disclose sufficient guidance as to how these could be used.

*Existence of working examples/specification:* The specification does not disclose for example compounds where R<sub>2</sub> and R' are each a cycle, aryl or heterocycle, or R<sub>1</sub> and R' together with a nitrogen form a ring. There is also no test data for any of the compounds of formula (II) in the specification. Thus, designing any of so many possibilities of the compound of formula (II) as generically claimed and predicting the outcome seems impossible. Currently, a clear evaluation of toxicity and activity of the compounds with the many claimed variables is needed.

*The skill of those in the art:* The examiner notes that the knowledge of level of skill in this art would not permit one skilled in this art to assert an intended use for the different variations of compounds of formula (II) claimed and the skilled artisan would not immediately envisage the invention claimed. Additionally, the prior art and disclosure are silent about examples of such compounds other than the mentioned and how to make or how to use them.

*Amount of experimentation necessary:* The invention is pharmaceutical in nature as it involves treatment of different diseases with the claimed compounds.

In order to practice the claimed invention one of ordinary skill in the art would need to make the very variable claimed compounds by different methods, test them for their activity (including *in vivo*), investigate their bioavailability, and investigate the effective amount of compound(s) and regimen of administration needed for treating the variable diseases.

It would require undue experimentation for one of ordinary skill in the art to practice the claimed invention in the full broad scope recited in the claims. Therefore, the claimed invention is not fully enabled by the instant specification.

## Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626